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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,867	03/15/2001	Michael John Bradley Kutryk	1133279-0003	5578

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EXAMINER
CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
3738	13

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/808,867	KUTRYK ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *6,10-17,19,26,33-37,40,42,46,48 and 51-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,18,20-25,27,29-32,38,39,41,43-45,47,49 and 50* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The Preliminary Amendment filed 7/19/01 has been entered as Paper No. 4. Claims 52-55 have been added. Claims 1-55 are currently pending in the application.

Election/Restrictions

2. Applicant's election with traverse of (1)(a) of the vessel type being an artery and (2)(b) of the matrix being attached covalently in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the traversal of the restriction for Groups I-IV is tantamount to the traversal of the species requirement and that the species requirement is inseparable from the restriction requirement. This is not found persuasive because the species requirement is indeed separable from the restriction requirement. The type of medical device (stent or graft), matrix material (synthetic, natural, fullerene), matrix attachment (noncovalently or covalently), antibody attachment (noncovalently coated or tethered covalently), and vessel type (artery or vein) are all *patentably distinct* species, no matter what invention they are dependent on. Because the previous restriction requirement of Groups I-IV has been withdrawn and all inventions will be examined, those subspecies under species that were originally dependent on the non-elected groups must now be elected from because they remain patentable distinct species.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant has elected the following: medical device (stent), matrix (fullerene), antibody attachment (covalent), vessel type (artery) and matrix attachment (covalently). Applicant asserts

that claims 1-25, 27-39, 41, 43-47 and 49-51 are readable on the elected embodiments. After reviewing the claims, the examiner has further withdrawn the proceeding claims for the following reasons:

1) Claims 6, 46 and 51 for being withdrawn to non-elected medical device of a graft

2) Claims 10-17, 19, 33-37 and 52 and 53 for being drawn to non-elected matrix materials of synthetic and naturally occurring materials

3) Claim 26 for being drawn to non-elected antibody attachment of noncovalently coated

4) Claim 40 for being drawn to non-elected vessel type of a vein

5) Claims 42 and 48 for being drawn to non-elected matrix attachment of noncovalently

6) Claims 54 and 55, while the specification discloses that fullerene matrix may be mixed with PTFE or ePTFE, these claims to do not claim the elected embodiment of fullerene

4. The claims being withdrawn from consideration are 6, 10-17, 19, 26, 33-37, 40, 42, 46, 48 and 51-55. The claims being considered for further examination on the merits are 1-5, 7-9, 18, 20-25, 27-32, 38, 39, 41, 43-45, 47, 49 and 50.

Information Disclosure Statement

5. The information disclosure statements filed 10/25/01 and 11/7/01 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. They have been placed in the application file, but the information referred to therein has not been considered. Copies of (1) Harrison's Principles of Internal Medicine, 14th Edition, 1998, (2) *Biological Aspects of Fullerenes* by Stephen R. Wilson, and (3) *Biology of*

Endothelial Cells by Jaffe, E. A. were not provided, and therefore, not considered by the examiner. A copy of Jaffe, E. A. "Cell Biology of Endothelial Cells" in Human Pathology, Vol. 18, No. 3, March 1987 was included, but not considered because it was not listed on the PTO-1449.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The declaration does not claim priority to provisional applications 60/189,674 filed 3/15/00 and 60/201,789 filed 5/4/00.

Specification

7. The specification is objected to. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of *50 to 150 words*. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using *phrases which can be implied*, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

"This invention provides" uses legal phraseology that can be implied, and should therefore, be removed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 27, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 2 and 27 recite the limitation "the last layer" in line 2. There is insufficient antecedent basis for this limitation in the claims.

10. Claim 43 recites the limitation "the first layer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 41, 45, 47 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al. (USPN 5,688,486).

Watson et al. discloses a coated medical device with all the elements of claims 41 and 47. See column 17, lines 55-56 for a medical device being coated with at least one layer of a matrix comprising a fullerene ranging from about C60 to about C100 (see column 18, Example 1). See column 5, lines 43-48 for fullerene being arranged as a nanotube.

Claims 45 and 50, see column 17, lines 55-57 for medical device being a stent.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. in view of Mirkin et al. (USPN 5,338,571 as cited in applicant's IDS).

Watson et al. discloses a coated medical device with all the elements of claims 41 and 47, but is silent to the first layer of the matrix being covalently attached to the medical device, as required by claims 43 and 49. Mirkin discloses covalently attaching a first layer of fullerene C60 to a substrate surface in order to exploit the potentially useful properties of fullerene films. See column 1, lines 24-28. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Mirkin et al. to modify the coated medical device of Watson et al. by covalently attaching the first layer of the fullerene matrix to the medical device in order to exploit the potentially useful properties of fullerene films.

15. Claims 1, 2, 4, 7, 9, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekker et al. (*Improved Adhesion and Proliferation of Human Endothelial Cells on Polyethylene Precoated with Monoclonal Antibodies Directed Against Cell Membrane Antigens*

and Extracellular Matrix Proteins, as cited in applicant's IDS) in view of Richmond et al. (USPN 5,310,669 as cited in applicant's IDS).

Dekker et al. discloses a coated medical device and method for treating mammals for obstruction of a vessel with all the elements of claims 1 and 38, but is silent to the medical device being coated with at least one layer of a matrix comprising fullerene ranging from about C60 to about C100. See *Summary* and *Introduction* for treating mammals for obstruction of a vessel using a medical device (vascular graft) coated with a therapeutically effective amount of at least one type of antibody, which reacts with an endothelial cell antigen. Richmond et al. teaches a substrate coated with a matrix comprising fullerene C60 with an antibody bound thereto (claim 2; column 5, lines36-37) in order to facilitate cell attachment and growth, as well as generate highly reactive singlet oxygen, which is useful in the process of studying cell membrane composition e.g., cholesterol content. See column 3, lines 31-35 and columns 3-4, lines 65-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Richmond et al. to modify the method of Dekker et al. by including to the medical device antibody coating at least one layer of matrix comprising a fullerene of about C60 in order to facilitate cell attachment and growth, as well as generate highly reactive singlet oxygen, which is useful in the process of studying cell membrane composition e.g., cholesterol content.

Claims 4 and 9, see *Summary* for antibody being the monoclonal antibody, $F(ab')_2$ fragments.

Claim 7, see pages 716-717 under *Cell Adhesion and Proliferation* for human endothelial cells.

Claim 39, see line 2 of *Introduction* for vessel being an artery.

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekker et al. and Richmond et al. as applied to claim 1 above, and further in view of Watson et al.

Dekker et al., as modified by Richmond et al., discloses a coated medical device with all the elements of claim 1, but is silent to the medical device being a stent. Watson et al. teaches a stent coated with a fullerene ranging from about C60 to about C100 in order to provide the stent with singlet oxygen generators. See column 17, lines 55-63. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Watson et al. to coat a stent with the coating of Dekker et al. in order to provide the stent with singlet oxygen generators. These generators are useful particularly in the areas where stents are required in the process of studying cell membrane composition e.g., cholesterol content.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekker et al. and Richmond et al. as applied to claims 1 and 4 above, and further in view of Asahara et al. (*Isolation of Pututive Progenitor Endothelial Cells for Angiogenesis*, as cited in applicant's IDS).

Dekker et al., as modified by Richmond et al., discloses a coated medical device with all the elements of claim 1, but is silent to the monoclonal antibody reacting with endothelial cell surface antigen CD34, as required by claim 8. Asahara et al. teaches, as disclosed by applicant on page 15 of the specification, using anti-CD34 monoclonal antibodies attached to a solid support in order to capture progenitor endothelial cells that are capable of differentiating into endothelial cells. It would have been obvious to one of ordinary skill in the art at the time of

applicant's invention to look to the teachings of Asahara et al. to modify the monoclonal antibody of Dekker et al. and Richmond et al. so that it reacts with the endothelial cell surface antigen CD34 in order for it to capture progenitor endothelial cells that are capable of differentiating into endothelial cells. This increases endothelial cell proliferation and graft patency.

18. Claims 18, 20-22, 24, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al. in view of Dekker.

Richmond et al. discloses a composition and method of coating a substrate with all the elements of claims 18 and 25, but is silent to the antibody reacting with an endothelial cell antigen and the substrate being a medical device. See abstract and column 5, lines 24-37 for a composition that is capable and suitable of being coated to a medical device (the word "for" is intended use language only) and method for coating a substrate comprising a matrix (fullerene) and a therapeutically effective amount of at least one type of antibody bound thereto (claim 27). Dekker et al. teaches coating a medical device (vascular graft) with mixtures of monoclonal antibody $F(ab')_2$ fragments (claims 21 and 24) that react with a human endothelial cell antigen (claim 22) in order to promote growth and proliferation of endothelial cells and improve the patency of graft. See *Summary* on page 715 and *Cell Adhesion and Proliferation* on pages 716-717. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Dekker et al. to make the substrate of Richmond et al. a medical device and the antibody monoclonal antibody $F(ab')_2$ fragments that react with a human

endothelial cell antigen in order to promote growth and proliferation of endothelial cells and improve graft patency.

Claim 20, see column 3, lines 8-14 for fullerene within the required range.

19. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al. and Dekker et al. as applied to claims 18 and 21 above, and further in view of Asahara et al.

Richmond et al., as modified by Dekker et al., discloses a composition with all the elements of claim 18, but is silent to the monoclonal antibody reacting with endothelial cell surface antigen CD34, as required by claim 23. Asahara et al. teaches, as disclosed by applicant on page 15 of the specification, using anti-CD34 monoclonal antibodies attached to a solid support in order to capture progenitor endothelial cells that are capable of differentiating into endothelial cells. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Asahara et al. to modify the monoclonal antibody of Richmond et al. and Dekker et al. so that it reacts with the endothelial cell surface antigen CD34 in order for it to capture progenitor endothelial cells that are capable of differentiating into endothelial cells. This increases endothelial cell proliferation and graft patency.

20. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekker et al. in view of Richmond et al. and Bos et al. (*Small-Diameter Vascular Graft Prosthesis: Current Status*, as cited in applicant's IDS).

Dekker et al. discloses a method for treating mammals with obstructed arteries with all the elements of claim 29, but is silent to the method specifically treating for atherosclerosis and the medical device being coated with at least one layer of a matrix comprising fullerene ranging from about C60 to about C100. See *Summary* and *Introduction* for treating mammals for obstruction of a vessel using a medical device (vascular graft) coated with a therapeutically effective amount of at least one type of antibody, which reacts with an endothelial cell antigen. Richmond et al. teaches a substrate coated with a matrix comprising fullerene C60 with an antibody in order to facilitate cell attachment and growth, as well as generate highly reactive singlet oxygen, which is useful in the process of studying cell membrane composition e.g., cholesterol content. See column 3, lines 31-35 and columns 3-4, lines 65-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Richmond et al. to modify the method of Dekker et al. by including to the medical device antibody coating at least one layer of matrix comprising a fullerene of about C60 in order to facilitate cell attachment and growth, as well as generate highly reactive singlet oxygen, which is useful in the process of studying cell membrane composition e.g., cholesterol content. Bos et al. teaches that it is old and well known in the art to treat mammals for atherosclerosis with grafts under *Introduction* (first paragraph). It would have been obvious, therefore, to one of ordinary skill in the art to use the graft of Dekker et al. to treat atherosclerosis, specifically in the coronary artery (claim 31), because it is customary to do so.

Claims 30 and 32, see *Summary* of Dekker et al. for antibody being the monoclonal antibody $F(ab')_2$ fragments.

Allowable Subject Matter

21. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. NO ! rejected under 103(a).

22. Claims 2and 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

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